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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/757,202	01/09/2001	Robert J. Miller	GC-10.6-CON	8824
24536	7590	06/30/2004	EXAMINER	
GENZYME CORPORATION LEGAL DEPARTMENT 15 PLEASANT ST CONNECTOR FRAMINGHAM, MA 01701-9322			WHITE, EVERETT NMN	
			ART UNIT	PAPER NUMBER
			1623	

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/757,202

Applicant(s)

MILLER ET AL.

Examiner

EVERETT WHITE

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 15-30 and 60-76 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 15-30 is/are allowed.
- 6) ☒ Claim(s) 60-76 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. The reply filed April 12, 2004 and the Terminal Disclaimers have been received, entered and carefully considered. The reply affects the instant application accordingly:
  - (A) Comments regarding Office Action have been provided drawn to:
    - (i) Nonstatutory double patenting rejection, which has been withdrawn.
2. Claims 15-30 and 60-76 are pending in the case.
3. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

### ***Finality Withdrawn***

4. The finality of the rejection of the last Office action is withdrawn in view of the following new grounds of rejection.

### ***Double Patenting***

5. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

6. Claims 60-76 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 5-17 of prior U.S. Patent No. 5,760,200. This is a double patenting rejection.

Both, instant Claims 60-76 and Claims 5-17 of US Patent No. 5,760,200 to Miller et al are drawn to analogous water insoluble compositions wherein both documents discloses dependent claims which set forth that said compositions may be in the form of a gel, fibers, membrane or foam, and set forth that the compositions further comprises a drug dispersed within the compositions. The dependent claims in both documents also

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set forth claims directed to analogous water insoluble compositions in the form of product-by-process claims.

7. Applicant's arguments with respect to claims 60-76 have been considered but are moot in view of the new ground(s) of rejection.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

9. Claims 60-62 and 67-76 are rejected under 35 U.S.C. 102(b) as being anticipated by Herman et al (US Patent No. 4,308,416).

Applicants claim a water insoluble composition in the form of a product-by-process. The Office considers product-by-process claims as product claims. Applicants are reminded that process limitations cannot impart patentability to a product that is not patentably distinguished over the prior art. *In re Thorpe et al.* (CAFC 1985), supra; *In re Dike* (CCPA 1968) 394 F2d 584, 157 USPQ 581; *Tri-Wall Containers, Inc. v. United*

*States et al.* (Ct Cls 1969) 408 F2d 748, 161 USPQ 116; *In re Brown et al.* (CCPA 1972) 450 F2d 531, 173 USPQ 685; *Ex parte Edwards et al.* (BPAI 1986) 231 USPQ 981. Additional limitations set forth in the dependent claims include the composition being in the form of a gel or fibers.

The Herman et al patent discloses water-insoluble compositions under the subheading "Comparative Examples A to G" beginning at column 10, line 22. See Table I, which sets forth the products that include Comparative A as fibers of internally crosslinked sodium carboxymethylcellulose. Also see the water insoluble products of Comparatives C and D, which have been gelled in water. The examples in Table 1 shows that water-insoluble compositions in the form of a gel and fibers anticipates the water-insoluble composition of instant Claims 60-62. Claims 67-76 are noted but do not further limit the composition, per se, since these claims only set forth process limitations. Process limitations cannot impart patentability to a product that is not patentably distinguished over the prior art.

10. Applicant's arguments with respect to claims 60-62 and 67-76 have been considered but are moot in view of the new ground(s) of rejection.

11. Claims 60 and 65-76 are rejected under 35 U.S.C. 102(e) as being anticipated by Alderman (US Patent No. 4,308,416).

Applicants claim a water insoluble composition in the form of a product-by-process. The Office considers product-by-process claims as product claims. Applicants are reminded that process limitations cannot impart patentability to a product that is not patentably distinguished over the prior art. *In re Thorpe et al.* (CAFC 1985), supra; *In re Dike* (CCPA 1968) 394 F2d 584, 157 USPQ 581; *Tri-Wall Containers, Inc. v. United States et al.* (Ct Cls 1969) 408 F2d 748, 161 USPQ 116; *In re Brown et al.* (CCPA 1972) 450 F2d 531, 173 USPQ 685; *Ex parte Edwards et al.* (BPAI 1986) 231 USPQ 981. Additional limitations set forth in the dependent claims include the composition further comprising a drug dispersed within the composition.

The Alderman patent discloses water-insoluble compositions that include naproxyn and ibuprofen (see column 3, lines 25 and 26), which anticipate the instantly

claimed water insoluble composition and the water insoluble composition further comprising a drug dispersed within the composition as set forth in instant Claims 65 and 66. Claims 67-76 are noted but do not further limit the composition, per se, since these claims only set forth process limitations. Process limitations cannot impart patentability to a product that is not patentably distinguished over the prior art.

12. Applicant's arguments with respect to claims 60 and 65-76 have been considered but are moot in view of the new ground(s) of rejection.

13. Claims 60 and 64 are rejected under 35 U.S.C. 102(b) as being anticipated by Heyden et al (US Patent No. 4,127,512).

Applicants claim a water insoluble composition in the form of a product-by-process. An additional limitation set forth in the dependent claim includes the composition in the form of foam.

The Heyden et al patent discloses water-insoluble foam inhibitors (see column 1, 1<sup>st</sup> paragraph), which anticipate the instantly claimed water insoluble composition in the form of foam.

14. Applicant's arguments with respect to claims 60 and 64 have been considered but are moot in view of the new ground(s) of rejection.

15. Claims 60 and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Sano et al (US Patent No. 4,046,843).

Applicants claim a water insoluble composition in the form of a product-by-process. An additional limitation set forth in the dependent claim includes the composition in the form of a membrane.

The Sano et al patent discloses a water-insoluble membrane (see column 2, 2<sup>nd</sup> paragraph), which anticipate the instantly claimed water insoluble composition in the form of a membrane.

16. Applicant's arguments with respect to claims 60 and 63 have been considered but are moot in view of the new ground(s) of rejection.

***Allowable Subject Matter***

17. Claims 15-30 are allowed.

18. The following is a statement of reasons for the indication of allowable subject matter: The terminal disclaimers filed on April 12, 2004 to overcome the rejection over US Patent Nos. 5,760,200 and 6,174,999 have been reviewed and are accepted. The terminal disclaimer has been recorded. The terminal disclaimers put instant Claims 15-30 in condition for allowance.

***Summary***

19. Claims 15-30 are allowed; Claims 60-76 are rejected.

***Examiner's Telephone Number, Fax Number, and Other Information***


20. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit our website at [www.uspto.gov](http://www.uspto.gov) and click on the button "Patent Electronic Business Center" for more information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (571) 272-0660. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached on (571) 272-0661. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

E.White



James O. Wilson  
Supervisory Primary Examiner  
Technology Center 1600